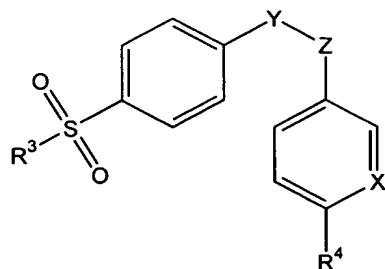


## WHAT IS CLAIMED IS:

1. An orally deliverable pharmaceutical composition comprising
  - (a) a drug of low water solubility;
  - (b) a pharmaceutically acceptable solvent liquid; and
  - 5 (c) a turbidity-decreasing polymer;

wherein at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid, and wherein said polymer is present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid.
- 10 2. The composition of Claim 1 wherein the drug is present in a therapeutically effective amount.
3. The composition of Claim 1 wherein the drug is present in a total amount of about 1% to about 75% by weight of the composition.
4. The composition of Claim 1 wherein at least about 15% of the drug is present in 15 the solvent liquid in dissolved or solubilized form.
5. The composition of Claim 1 wherein substantially all of the drug is present in the solvent liquid in dissolved or solubilized form.
6. The composition of Claim 1 wherein the drug is a selective cyclooxygenase-2 inhibitory drug.
- 20 7. The composition of Claim 6 wherein the selective cyclooxygenase-2 inhibitory drug is a compound having the formula



where  $\text{R}^3$  is a methyl or amino group,  $\text{R}^4$  is hydrogen or a  $\text{C}_{1-4}$  alkyl or alkoxy group,  $\text{X}$  is N or  $\text{CR}^5$  where  $\text{R}^5$  is hydrogen or halogen, and  $\text{Y}$  and  $\text{Z}$  are independently carbon or nitrogen atoms defining adjacent atoms of a five- to 25 six-membered ring.

- six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups; or a prodrug of such a compound.
8. The composition of Claim 7 wherein the five- to six-membered ring is selected from cyclopentenone, furanone, methylpyrazole, isoxazole and pyridine rings substituted at no more than one position.
- 5
9. The composition of Claim 6 wherein the selective cyclooxygenase-2 inhibitory drug is selected from the group consisting of celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.
- 10
10. The composition of Claim 9 wherein the selective cyclooxygenase-2 inhibitory drug is celecoxib.
11. The composition of Claim 19 that comprises one or more dose units each comprising about 10 mg to about 1000 mg of celecoxib.
- 15
12. The composition of Claim 10 that comprises one or more dose units each comprising about 50 mg to about 400 mg of celecoxib.
13. The composition of Claim 9 wherein the drug is valdecoxib.
14. The composition of Claim 1 wherein the turbidity-decreasing polymer is selected from the group consisting of polyvinylpyrrolidone and cellulosic polymers.
- 20
15. The composition of Claim 1 wherein the turbidity-decreasing polymer is a cellulosic polymer selected from the group consisting of sodium carboxymethylcellulose, hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose and ethylcellulose.
- 25
16. The composition of Claim 15 wherein the cellulosic polymer is hydroxypropylmethylcellulose.
17. The composition of Claim 16 wherein the hydroxypropylmethylcellulose has about 15% to about 35% methoxyl substitution and about 3% to about 15%

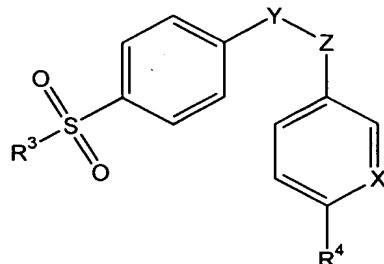
hydroxypropoxyl substitution.

- 18 19. The composition of Claim 16 wherein the hydroxypropylmethylcellulose has about 19% to about 30% methoxyl substitution and about 4% to about 12% hydroxypropoxyl substitution.
- 19 20. The composition of Claim 16 wherein the hydroxypropylmethylcellulose has about 19% to about 24% methoxyl substitution and about 7% to about 12% hydroxypropoxyl substitution.
- 20 21. The composition of Claim 6 further comprising a vasomodulator, wherein the selective cyclooxygenase-2 inhibitory drug and the vasomodulator are present in total and relative amounts effective to relieve pain in headache or migraine.  
10
- 21 22. The composition of Claim 6 further comprising an alkylxanthine compound, wherein the selective cyclooxygenase-2 inhibitory drug and the alkylxanthine compound are present in total and relative amounts effective to relieve pain in headache or migraine.
- 22 23. The composition of Claim 22 where in the alkylxanthine compound is selected from the group consisting of caffeine, theophylline and theobromine.
- 23 24. The composition of Claim 22 wherein the alkylxanthine compound is caffeine.
- 24 25. The composition of Claim 1 wherein the turbidity-decreasing polymer is present in the solvent liquid in an amount of about 1% to about 20% by weight of the solvent liquid.  
20
- 25 26. The composition of Claim 1 wherein the turbidity-decreasing polymer is present in the solvent liquid in an amount of about 1% to about 15% by weight of the solvent liquid.
- 26 27. The composition of Claim 1 that is an imbibable liquid.
- 27 28. The composition of Claim 1 further comprising a water-soluble capsule wall wherein the drug and solvent liquid are encapsulated.
- 28 29. The composition of Claim 28 wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 5% to about 100% by weight of the wall.

30. The composition of Claim 28 wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 15% to about 100% by weight of the wall.
31. The composition of Claim 1 wherein the solvent liquid comprises a solvent selected from the group consisting of pharmaceutically acceptable glycols and glycol ethers.
- 5 32. The composition of Claim 31 wherein the solvent is polyethylene glycol.
33. The composition of Claim 32 wherein the polyethylene glycol has an average molecular weight of about 100 to about 10,000.
- 10 34. The composition of Claim 32 wherein the polyethylene glycol has an average molecular weight of about 100 to about 1,000.
35. The composition of Claim 32 wherein the polyethylene glycol has an average molecular weight of about 375 to about 450.
36. The composition of Claim 32 wherein the polyethylene glycol is of liquid grade.
- 15 37. An orally deliverable pharmaceutical composition comprising  
36 (a) a drug of low water solubility;  
(b) a pharmaceutically acceptable solvent liquid; and  
(c) a cellulosic polymer;  
wherein at least a substantial portion of the drug is in dissolved or solubilized form in the solvent liquid, and wherein said cellulosic polymer is present in an amount sufficient to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid.
- 20 38. The composition of Claim 37 wherein the drug is present in a therapeutically effective amount.
- 25 39. The composition of Claim 37 wherein the drug is present in a total amount of about 1% to about 75% by weight of the composition.
40. The composition of Claim 37 wherein at least about 15% of the drug is present in the solvent liquid in dissolved or solubilized form.
41. The composition of Claim 37 wherein substantially all of the drug is present in

the solvent liquid in dissolved or solubilized form.

42. The composition of Claim 37 wherein the drug is a selective cyclooxygenase-2 inhibitory drug.
43. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is a compound having the formula



- where  $R^3$  is a methyl or amino group,  $R^4$  is hydrogen or a  $C_{1-4}$  alkyl or alkoxy group,  $X$  is N or  $CR^5$  where  $R^5$  is hydrogen or halogen, and  $Y$  and  $Z$  are independently carbon or nitrogen atoms defining adjacent atoms of a five- to six-membered ring that is unsubstituted or substituted at one or more positions with oxo, halo, methyl or halomethyl groups; or a prodrug of such a compound.
- 10 44. The composition of Claim 43 wherein the five- to six-membered ring is selected from cyclopentenone, furanone, methylpyrazole, isoxazole and pyridine rings substituted at no more than one position.
  - 15 45. The composition of Claim 42 wherein the selective cyclooxygenase-2 inhibitory drug is selected from the group consisting of celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.
  - 20 46. The composition of Claim 45 wherein the selective cyclooxygenase-2 inhibitory drug is celecoxib.
  47. The composition of Claim 46 that comprises one or more dose units each comprising about 10 mg to about 1000 mg of celecoxib.
  - 25 48. The composition of Claim 46 that comprises one or more dose units each

- comprising about 50 mg to about 400 mg of celecoxib.
50. The composition of Claim 45 wherein the drug is valdecoxib.
51. The composition of Claim 37 wherein the cellulosic polymer is selected from the group consisting of sodium carboxymethylcellulose,
- 5 hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose, and ethylcellulose.
52. The composition of Claim 37 wherein the cellulosic polymer is hydroxypropylmethylcellulose.
53. The composition of Claim 52 wherein the hydroxypropylmethylcellulose has about 15% to about 35% methoxyl substitution and about 3% to about 15% hydroxypropoxyl substitution.
- 10 54. The composition of Claim 52 wherein the hydroxypropylmethylcellulose has about 19% to about 30% methoxyl substitution and about 4% to about 12% hydroxypropoxyl substitution.
- 15 55. The composition of Claim 52 wherein the hydroxypropylmethylcellulose has about 19% to about 24% methoxyl substitution and about 7% to about 12% hydroxypropoxyl substitution.
56. The composition of Claim 42 further comprising a vasomodulator, wherein the selective cyclooxygenase-2 inhibitory drug and the vasomodulator are present in total and relative amounts effective to relieve pain in headache or migraine.
- 20 57. The composition of Claim 42 further comprising an alkylxanthine compound, wherein the selective cyclooxygenase-2 inhibitory drug and the alkylxanthine compound are present in total and relative amounts effective to relieve pain in headache or migraine.
- 25 58. The composition of Claim 57 wherein the alkylxanthine compound is selected from the group consisting of caffeine, theophylline and theobromine.
59. The composition of Claim 58 wherein the alkylxanthine compound is caffeine.
60. The composition of Claim 37 wherein the cellulosic polymer is present in the solvent liquid in an amount of about 1% to about 20% by weight of the solvent

liquid.

61. The composition of Claim 37 wherein the cellulosic polymer is present in the solvent liquid in an amount of about 1% to about 15% by weight of the solvent liquid.
- 5     62. The composition of Claim 37 that is an imbibable liquid.
63. The composition of Claim 37 further comprising a water-soluble capsule wall wherein the drug and solvent liquid are encapsulated.
64. The composition of Claim 63 wherein the cellulosic polymer is present in the capsule wall in an amount of about 5% to about 100% by weight of the wall.
- 10    65. The composition of Claim 63 wherein the cellulosic polymer is present in the capsule wall in an amount of about 15% to about 100% by weight of the wall.
66. The composition of Claim 37 wherein the solvent liquid comprises a solvent selected from the group consisting of pharmaceutically acceptable glycols and glycol ethers.
- 15    67. The composition of Claim 66 wherein the solvent is polyethylene glycol.
68. The composition of Claim 67 wherein the polyethylene glycol has an average molecular weight of about 100 to about 10,000.
69. The composition of Claim 67 wherein the polyethylene glycol has an average molecular weight of about 100 to about 1,000.
- 20    70. The composition of Claim 67 wherein the polyethylene glycol has an average molecular weight of about 375 to about 450.
71. The composition of Claim 67 wherein the polyethylene glycol is of liquid grade.
72. An orally deliverable pharmaceutical composition comprising a drug of low water solubility in a high energy phase together with one or more pharmaceutically acceptable excipients, encapsulated within a capsule wall that comprises a turbidity-decreasing polymer in an amount effective to substantially inhibit crystallization and/or precipitation of the drug in simulated gastric fluid.
- 25    73. The composition of Claim 72 wherein the drug is a selective cyclooxygenase-2

- inhibitory drug.
74. The composition of Claim 73 wherein the selective cyclooxygenase-2 inhibitory drug is selected from the group consisting of celecoxib, deracoxib, valdecoxib, rofecoxib, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)phenyl]-2-cyclopenten-1-one, (S)-6,8-dichloro-2-(trifluoromethyl)-2H-1-benzopyran-3-carboxylic acid and 2-(3,4-difluorophenyl)-4-(3-hydroxy-3-methyl-1-butoxy)-5-[4-(methylsulfonyl)phenyl]-3-(2H)-pyridazinone.
- 5 75. The composition of Claim 74 wherein the selective cyclooxygenase-2 inhibitory drug is celecoxib.
- 10 76. The composition of Claim 72 wherein said high energy phase is an amorphous phase of the drug.
77. The composition of Claim 72 wherein said high energy phase is a salt of an acid or base form of the drug.
- 15 78. The composition of Claim 72 wherein the turbidity-decreasing polymer is a cellulosic polymer.
79. The composition of Claim 78 wherein the cellulosic polymer is selected from the group consisting of sodium carboxymethylcellulose, hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose, and ethylcellulose.
- 20 80. The composition of Claim 78 wherein the cellulosic polymer is hydroxypropylmethylcellulose.
81. The composition of Claim 80 wherein the hydroxypropylmethylcellulose has about 15% to about 35% methoxyl substitution and about 3% to about 15% hydroxypropoxyl substitution.
- 25 82. The composition of Claim 80 wherein the hydroxypropylmethylcellulose has about 19% to about 30% methoxyl substitution and about 4% to about 12% hydroxypropoxyl substitution.
83. The composition of Claim 80 wherein the hydroxypropylmethylcellulose has about 19% to about 24% methoxyl substitution and about 7% to about 12%

hydroxypropoxyl substitution.

84. The composition of Claim 72 wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 5% to about 100% by weight of the wall.
- 5      85. The composition of Claim 72 wherein the turbidity-decreasing polymer is present in the capsule wall in an amount of about 15% to about 100% by weight of the wall.
- 10     86. A method of treating a medical condition or disorder in a subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering to the subject a composition of Claim 6, Claim 42, or Claim 73.
- 15     87. A method of analgesia comprising orally administering, to a subject in need of analgesia, an effective pain-relieving amount of a composition of Claim 6, Claim 42, or Claim 73.
- 20     88. The method of Claim 87 wherein the subject suffers from headache or migraine and wherein there is further orally administered to the subject a vasomodulator, the selective cyclooxygenase-2 inhibitory drug and the vasomodulator being administered in total and relative amounts effective to relieve pain in the headache or migraine.
- 25     89. The method of Claim 88 wherein the vasomodulator is co-formulated with the selective cyclooxygenase-2 inhibitory drug.
90. The method of Claim 87 wherein the subject suffers from headache or migraine and wherein there is further orally administered to the subject an alkylxanthine compound, the selective cyclooxygenase-2 inhibitory drug and the alkylxanthine compound being administered in total and relative amounts effective to relieve pain in the headache or migraine.
- 25     91. The method of Claim 90 wherein the alkylxanthine compound is co-formulated with the selective cyclooxygenase-2 inhibitory drug.
92. The method of Claim 91 wherein the alkylxanthine compound is selected from the group consisting of caffeine, theophylline, and theobromine.

93. The method of Claim 91 wherein the alkylxanthine compound is caffeine.